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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,243	08/13/2001	Gust H. Bardy	003.0220.01	8992

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,243	Applicant(s) BARDY, GUST H.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/1/04 (Response and RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-14,16-23,25-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-14,16-23,25-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/03 & 4/1/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 4/1/04 has been entered.

Response to Amendment

2. The Applicant's arguments filed 4/1/04 have been fully considered. The rejection based on the 35 U.S.C. 102(e) Nelson (US 6155267) is withdrawn. The arguments related to the other 35 U.S.C. 103(a) rejections of record are responded to in the respective subsequent paragraphs.

Claim Rejections - 35 USC § 103

3. Claims 1-5, 10-14, 20-23 and 25-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Heemels et al. (US 5603331) and further in view of Brown (US 6168563).

Selker et al. disclose continuous monitoring using a predictive instrument.

As to claims 1-3 and 10-12, one or more clinical features (read as physiological measures) are monitored periodically to compute a change-of-condition measure (read as a

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patient status indicator). If the change-of-condition measure is above a threshold, an alarm notification (automated feedback) is generated (col. 1 @ 61 – col. 2 @ 11; col. 3 @ 55 – col. 4 @ 65). The monitoring device can be from a wide variety of monitoring devices including heart rate monitors (col. 12 @ 38-42).

As to claim 4 and 13, S-T segment depressions and elevations (the reference feedback) and the ECG wave (the physiological measure) are monitored by the system (col. 2 @ 54-60).

As to claims 5 and 14, the reference baseline is periodically revised (col. 5 @ 8-18).

As discussed in the previous four paragraphs of this action, Selker et al. disclose the claimed invention except for the monitoring device being implantable.

Heemels et al. teach cardiac data analysis using an implantable medical device (2) for the purpose of monitoring and collecting data such as heart rate variability. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an implantable medical device in the Selker et al. system in order to provide an alternate form for the cardiac data monitoring and collection device so the essential cardiac data collected and processed is disseminated to the care professional enabling diagnosis and prognosis (abstract; figure 2; col. 1 @ 59-61; col. 2 @ 13-33).

As discussed in the previous paragraph of this action, modified Selker et al. disclose the claimed invention except for: 1) storing all monitored data, and 2) monitoring and recording quality of life measurements.

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Brown discloses remote health monitoring.

As to storing data, Brown teaches health monitoring using memory for the purpose of storing all collected data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used memory to store all the data in the modified Selker et al. system in order to enable the health care provider to review the data in its entirety, record the data for later use, and/ or use the data to perform various analyses (col. 9 @ 2-19; col. 9 @ 61 – col. 10 @ 2).

As to the quality of life measurements, Brown teaches health monitoring using quality of life measurements for the purpose adding the subjective patient perspective information to the simultaneously measured physiological parameters so the caregiver has a more comprehensive understanding of the patient's condition. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used quality of life measurements in the modified Selker et al. system to enable the health care provider to more optimally monitor and manage the health care condition of the patient (abstract; figures 13 and 16; col. 6 @ 4-7; col. 9 @ 20-60).

The Applicant's arguments filed 4/4/04 have been fully considered, but they are not convincing.

In response to the Applicant's arguments that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the

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knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Selker et al., Heemels et al. and Brown all monitor patient's health status to provide patient care and are hence deemed to be combinable. Selker et al. teach monitoring clinical features/ physiological measures to determine a change of condition in the patient's health. Heemels et al. is combined with Selker et al. to teach implantable devices can be used to monitor patient's conditions. Brown is combined with modified Selker et al to teach the data storage and the use of quality of life measures to further define the patient's health status. The combination of Selker et al., Heemels et al. and Brown as discussed in the rejection above is deemed to have a reasonable expectation of success and teaches the instant invention.

In response to the Applicant's argument that the references fail to show certain features of the Applicant's invention, it is noted that the features upon which the Applicant relies (i.e., "regular recording during an initial observation period for developing a baseline", "quality of life measure both initial and subsequent", "storage of initial measures", "storage of subsequent measures", "a patient status indicator based on a baseline of measures", "subsequent measures", and "management of the baseline") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant asserts all the claim limitations listed below are not taught by the cited references. The Examiner disagrees. The claim limitations cited by the Applicant and the cited reference where the limitation is taught are noted below:

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- periodically receiving updated measures regularly recorded after the initial observation period (Selker et al. - col. 2 @ 3-4),
- a patient care record for the storage of all measures (Brown – col. 9 @ 2-8 , col. 9 @ 61 – col. 10 @ 2),
- initial quality of life measures (Selker et al. teach the notion of initial and subsequent measures (col. 1 @ 63-65 and col. 2 @ 3-4), Brown teaches the notion of monitoring both physiological measures and quality of life measures (col. 6 @ 4-7),
- subsequent quality of life measures (Selker et al. teach the notion of initial and subsequent measures (col. 1 @ 63-65 and col. 2 @ 3-4), Brown teaches the notion of monitoring both physiological measures and quality of life measures (col. 6 @ 4-7),
- updating the baseline (claim 5) (Selker et al. - col. 2 @ 3-4), and
- recording and storing physiological and quality of life measurements during an initial observation period and subsequent to the initial observation period (Selker et al. teach the notion of initial and subsequent measures (col. 1 @ 63-65; col. 2 @ 3-4), Brown teaches the notion of monitoring both physiological measures and quality of life measures (col. 6 @ 4-7).

Per the discussion above the rejection of record is deemed to teach the instant invention, hence the rejection of record stands.

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4. Claims 7-9 and 16-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Heemels et al. (US 5603331) and further in view of Brown (US 6168563) and further in view of Levine (US 4852570). As discussed in paragraph 3 of this action, modified Selker et al. disclose the claimed invention except for monitoring a prescribed exercise session and identifying abnormal activity or exercise.

Levine teaches medical physical analysis using a prescribed exercise session for the purpose of identifying abnormal activity or exercise indicative of illness or malfunction. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used monitoring of prescribed exercise sessions to identify abnormal activity or exercise in the modified Selker et al. system in order to provide an alternate measure that identifies long-term changes or trends in a patient's health (abstract; col. 10 @ 59 – col. 12 @ 38).

The Applicant's arguments filed 4/4/04 have been fully considered, but they are not convincing.

In response to the Applicant's arguments that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Selker et al., Heemels et al., Brown and Levine all monitor patient's health status to provide patient care and are hence deemed to be combinable. Selker et al. teach

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monitoring clinical features/ physiological measures to determine a change of condition in the patient's health. Heemels et al. is combined with Selker et al. to teach implantable devices can be used to monitor patient's conditions. Brown is combined with modified Selker et al to teach the data storage and the use of quality of life measures to further define the patient's health status. Levine is combined with modified Selker et al. to teach patient health status monitoring during an exercise session. The combination of Selker et al., Heemels et al., Brown and Levine as discussed in the rejection above is deemed to teach the instant invention and the rejection of record stands.

5. Claims 19 and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Heemels et al. (US 5603331) in view of Brown (US 6168563) and further in view of Levine (US 4852570) and further in view of Selker et al. (US 6067466). As discussed in paragraphs 3 and 4 of this action, modified Selker et al. (US 5724983) disclose the claimed invention except for providing a computer-readable storage medium holding code for performing the methods of this invention.

Selker et al. (US 6067466) teach computer program transfer using a computer readable medium for the purpose of entering an analysis/ diagnostic program in a processing module or computer. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a computer readable medium in the modified Selker et al. (US 5724983) system in order to provide a typical means of entering the analysis/ diagnostic program into a computer so the program is efficiently and effectively read/ loaded into the processor module/ computer (col. 3 @ 27-37 and 54-57).

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The Applicant's arguments filed 4/4/04 have been fully considered, but they are not convincing.

The Applicant assert again in this section of the rejection that Selker I, Heemels, Brown and Levine are not combinable. This argument was addressed at the conclusion of paragraph 4.

In response to the Applicant's argument that the references fail to show certain features of the Applicant's invention, it is noted that the features upon which the Applicant relies (i.e., "regular recording during an initial observation period for developing a baseline", "quality of life measure both initial and subsequent", "storage of initial measures", "storage of subsequent measures", "a patient status indicator based on a baseline of measures", "subsequent measures", and "management of the baseline") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant asserts all the claim limitations listed below are not taught by the cited references. The Examiner disagrees. The claim limitations cited by the Applicant and the cited reference where the limitation is taught are noted below:

- periodically receiving updated measures regularly recorded after the initial observation period (Selker et al. I - col. 2 @ 3-4),
- a patient care record for the storage of all measures (Brown – col. 9 @ 2-8 , col. 9 @ 61 – col. 10 @ 2),
- initial quality of life measures (Selker et al. I teach the notion of initial and subsequent measures (col. 1 @ 63-65 and col. 2 @ 3-4), Brown teaches the

notion of monitoring both physiological measures and quality of life measures
(col. 6 @ 4-7),

- subsequent quality of life measures (Selker et al. I teach the notion of initial and subsequent measures (col. 1 @ 63-65 and col. 2 @ 3-4), Brown teaches the notion of monitoring both physiological measures and quality of life measures (col. 6 @ 4-7),
- updating the baseline (claim 5) (Selker et al. I - col. 2 @ 3-4), and
- (summarizing several limitations) recording and storing physiological and quality of life measurements during an initial observation period and subsequent to the initial observation period (Selker et al. I teach the notion of initial and subsequent measures (col. 1 @ 63-65 and col. 2 @ 3-4), Brown teaches the notion of monitoring both physiological measures and quality of life measures (col. 6 @ 4-7).

Per the discussion above the rejection of record is deemed to teach the instant invention, hence the rejection of record stands.

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Conclusion

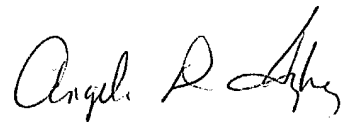
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

ffo
6/16/04



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